Panel Discussion: Fighting HAIs and MDROs with UV-C Using Industry, Health Care and Federal Collaboration

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The venue was the IUVA Americas Conference in Austin, Texas. At that conference, on Feb. 5, a panel was convened to discuss "Fighting HAIs and MDROs with UV-C Using Industry, Health Care and Federal Collaboration." The end goal was to help further the development, credibility and acceptance of UV antimicrobial capabilities in the fight against HAIs in our nation. The question is: Would industry-wide efficacy standards for UV antimicrobial disinfection devices help make this happen sooner?

Participating in the panel, as seen in Table 1, were three MDs to discuss issues from the health care perspective; two PhDs to discuss the current and future commercial aspects of UV-C technologies; and an attorney from the Federal Trade Commission to discuss current federal enforcement practices against unfair and deceptive practices. Moderating the panel and facilitating audience questions was incoming IUVA President Oliver Lawal.

Table 1. Panel members at the IUVA Americas Conference

Panel member	Experience
Dr. Richard Martinello (Yale-New Haven Hospital)	Acquiring and getting approval for UV antimicrobial devices in fighting HAIs from a hospital administrator perspective on UV device acquisitions.
Dr. David Pegues (U. of Pennsylvania Health System)	Recently conducted studies that highlighted the complexities and difficulties in testing UV antimicrobial devices.
Dr. Chetan Jinadatha (Texas A&M Health Science Center)	Brought insights into medical testing requirements and practices applied to UV antimicrobial devices.
James Golder (Federal Trade Commission, Dallas)	Recent FTC actions regarding misleading advertising by UV device companies. Brought insights into how efficacy standards could be applied to prevent consumer issues.
Dr. Shelly Miller (Univ. of Colorado)	Developing performance standards with ASHRAE involving UV technologies. Brought insights into how voluntary industry standards are developed and implemented.
Dr. Jennifer Pagan (AquiSense Technologies)	Developing and bringing to market new UV LED technologies. Brought insights into LED and similar new technology trends and possible applications.

The panel was convened to explore the potential for and issues around developing industry consensus based efficacy standards for UV-C antimicrobial devices used to combat hospital acquired infections (HAIs) and multiple drug-resistant organisms (MDROs). Facts driving the discussion included:

- In the US, we lose almost 99,000 people per year to hospital-acquired infections (HAIs), for example, MRSA, *C. diff*, *Acinetobacter*, *E. coli*, vancomycin-resistant enterococcus (VRE) and other bacteria resistant to first-line antibiotics.
- Medical research has shown that UV antimicrobial disinfection devices are effective tools in fighting HAIs, yet acceptance and fielding of UV technologies has been slow, in part due to the complexities of evaluating the efficacy between competing devices.
- All antimicrobial products and devices, not used to directly treat medical conditions, are regulated by EPA, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- FIFRA regulations include efficacy standards for antimicrobial products (e.g., cleaning chemicals, sterilizers, etc.), ranging from
  - "Sterilants" (e.g., 100 percent disinfected 100 percent of the time), to
  - "Disinfectants" (e.g., 100 percent disinfected 98 percent of the time), to
  - "Sanitizers" (e.g., 99.9 percent disinfected)
- Currently there are no FIFRA efficacy standards for our UV antimicrobial devices, only a requirement that manufacturers register with the EPA.

During the panel presentations, the current situation was characterized as a "Wild West" market due to the lack of standard metrics for use by scientists investigating the microbial outcomes, making it difficult to compare systems. Large emphasis was placed on the difficulties in making large capital investment decisions when there were questions about if UV-C devices can reliably disinfect in a hospital environment, how durable are they, how much does their use add to room turnaround times, and does their use actually result in positive patient outcomes

(i.e., actual reductions in HAI infection rates)? Is the premium cost for units with sophisticated engineering worth it?

This led to discussions of the significant cost/benefit uncertainties, which make the decision process and successful implementation long, drawn-out and painful for hospitals, already viewed as "the most expensive hotels in town."

Proper implementation of UV-C technology is as important as selecting the UV device itself. Questions abound, such as how best to monitor usage of UV-C devices? Should all rooms be treated or only MDRO rooms? What training is required and how will using the devices impact staffing (both union and non-union)? That the responsibility and ultimate ownership of the devices and the results they deliver is often in doubt (e.g., is the owner infection control? patient quality? environmental services? operations?) further clouds the issues around which technology yields the best return-on-investment.

In addition to issues around ROIs and existing regulations or lack thereof, the role of the federal government in protecting consumers and competition from unfair or deceptive practices also was discussed. The Federal Trade Commission (FTC) has broad authority to prevent unfair and deceptive acts or practices in or affecting commerce, to include false and deceptive advertising. This means that any health benefit, performance or efficacy claims must be true and backed by sound scientific evidence, to include testing, which must have real-world applicability. In short, if a company claims its UV device kills 99 percent of X, Y and Z, then it must have competent and reliable scientific evidence that proves its UV device kills 99 percent of X, Y and Z.

As for current state of the UV-C industry, upper room UV applications have been used in health care facilities to combat tuberculosis since the late 1940s, and UV technology is widely applied in water purification systems worldwide. Standards exist for UV application testing in both air handling systems (e.g., ASHRAE SPC-185.1 and .2) and drinking water systems (e.g., NSF/ANSI 55). As for developing such standards, it took ASHRAE approximately three years to develop an airborne efficacy testing plan now used for air handling systems.

Because no similar standards exist for surfaces, resulting in the current "Wild West" mentality, the industry has avoided significant investment in developing the UV devices for surface treatment. If such standards were developed, they would be welcomed by the industry, assuming they would provide a means for standardized testing that would be systematic and measurable, giving industry a clear, unambiguous target for acceptable product performance, and a better means for assessing the competing business priorities between pursuit of air- vs. water- vs. surface-focused technologies.

As a result of the panel and the ensuing discussions – with some of the questions and comments in Table 2 below – several follow-up actions are underway. One is the development of a CRADA proposal by the author for consideration by IUVA that would be submitted to EPA and other agencies for their support in developing UV-C industry-based consensus standards. In consideration of the panel and previous articles, SPIE (formerly the Society of Photo-Optical Instrumentation Engineers) is launching a new conference at the SPIE Photonics West 2018 entitled "Photonic diagnosis and treatment of infections and Inflammatory diseases" and has issued an invitation for an abstract on the topic of UV-C standards.

Table 2. A sample of audience questions and comments

Question	Comment
Are there consultants who can help in making selection decisions for UV technologies?	Not as yet, as more evidence-based data is needed, to include some foundational work to help develop the standards.
Are we clear on what the problem is to be regulated? What needs to be cleaned, and how "clean" is clean?	CDC has a list of 15 to 20 targeted high-touch surfaces in hospital rooms that are top priority. The preliminary focus is on C-diff and MRSA, and what's required to achieve Log-3 (99.9% clean) in the terminal cleaning process (i.e., final room cleaning prior to moving in a new patient). However, this has not been formalized.
Are incoming water outlets a source of HAIs?	With the exception of *Legionella*/ Legionnaires disease, classical water-associated pathogens are not considered serious players in causing HAIs.

And, perhaps mostly importantly, investigators from Yale University, the University of Colorado and Boston University are pursuing a grant from the Agency for Health Care Research and Quality to better understand the outcomes of UV-C surface disinfection complex lab and real-world health care settings where different materials, room size and variance in angles and shadowing impact UV-C effectiveness. These findings will be used to derive mathematical models of UV-C function that then can be generalized to guide UV-C use in a variety of different spaces. This would be followed by a series of experiments and observations to update and improve the models, to be performed during the implementation of UV-C in a large academic hospital. The findings from this work and the modeling work then would be combined to develop a "toolkit" to guide health care facilities developing and implementing UV-C surface disinfection programs.

Updates on the results of these initiatives and others will be reported in future issues. ■